Inspection Report

Date of Inspection: 23 November 2010
Purpose of inspection: Renewal of Storage Licence
Length of inspection: 7 hours
Inspectors Mr W Lenton (HFEA, Chair)
Mr C Hall (HFEA)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 21 May 2010 and 21 January 2011.

Date of Executive Licensing Panel: 4 February 2011

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	The London Sperm Bank
Centre number	0011
Licence number	L0011/18/a
Centre address	99 Harley Street, London, W1G 6AQ, United Kingdom
Person Responsible	Dr Kamal Ahuja
Licence Holder	The London Sperm Bank
Date licence issued	01/04/2010
Licence expiry date	31/03/2011
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The London Sperm Bank (LSB), centre 0011 has been licensed by the HFEA since April 2010 for the procurement, distribution, processing and storage of sperm. It was formerly known as the Louis Hughes centre, which was originally licensed in 1992. This is a relatively small centre with a total of only three to four staff on site which, presently recruits sperm donors and provides donor sperm to fertility clinics throughout the UK.

The centre is located in the refurbished basement of 99 Harley Street, London. The premises consist of a semen preparation laboratory, three semen production rooms, an office, a staff kitchen and a large room doubling as a cryostore and administration room.

Between the time of the previous renewal inspection on 29 October 2009 and the follow-up inspection on 14 April 2010, the centre has undergone a number of significant changes, which include:

- a change of ownership and is now within the JD Healthcare umbrella of HFEA licensed centres (whilst retaining the same HFEA centre number, 0011)
- Dr Kamal Ahuja has successfully completed the PR Entry programme and has been appointed the new PR (Executive Licensing Panel 27 January 2010)
- a new Licence Holder has been appointed (Executive Licensing Panel 11 March 2010)
- new staff have been recruited and a new organisational structure developed
- the premises have been refurbished and some new equipment has been purchased, installed and commissioned.

Variation to Licence

N/A

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period
N/A – Storage only	N/A

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	N/A
Research	N/A

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR is suitable and whether he has discharged their duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

Recommendation to the Executive Licensing Panel

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance and one other area of non-compliance

Since the inspection on 23 November 2010, the PR has responded to the report and has provided an assurance that all three areas of non-compliance will be addressed by the dates specified. The inspection team are therefore satisfied that the centre is in the process of resolving the two major and one other area of non-compliance highlighted within the report and mentioned below;

- validation of critical equipment
- laboratory background air quality
- documented SOPs should be formulated

The inspection team considers that overall there is sufficient information available to recommend the renewal of this centres licence for a period of four years without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well. The centre has a witnessing section within its laboratory manual which describes both the purpose and practice of the processes undertaken during the procurement, processing, freezing, storage and distribution of samples within the centre. All relevant staff are trained in the process of witnessing and signed off as competent by the laboratory manager, evidence of which was observed during inspection. Evidence of witnessing was seen within donor records and found to be compliant with Standard Licence Condition T71 (SLC 71). Quality indicators have been established for witnessing and an audit is due to be undertaken in December 2010 as part of the ongoing audit schedule (SLC 35; 36).
What the centre could do better. Nothing noted

Donor recruitment, assessment and screening (Guidance Note 11)

What the centre does well.

Donor recruitment, assessment and screening (Guidance Note: 11)
Sperm donors are recruited via various websites including employment/student sites and the centres own website. At an initial interview/consultation any prospective donor is informed of the requirements needed to be accepted onto the programme including their personal commitment to repeatedly attend the centre for donations and screening/examinations.
Staff at the centre provided verbal evidence that donors are selected on the basis of age (18-40 years) and an audit of donor records showed that regulatory age requirements were met. A detailed documented health questionnaire meeting regulatory requirements, completed and signed by the donor, was seen to be stored in the donors' records. (SLC 52a)

Donor information literature details reasons why a prospective donor would not be accepted by the centre; the donor is asked to give signed confirmation that they understand and take responsibility for providing accurate and detailed information. Checklists in the donor records outline the information provided to the donor.

The centre provided a list of donor screening tests carried out before donation and subsequent storage. The listed screening tests were seen to be compliant with regulatory requirements (SLC 52) and performed by a laboratory accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd (SLC T53 (a)).

Upon request, from a centrally held information record, the centre is able to provide donors with details such as, number/sex and year of births associated with their donation (Act Schedule 3; 31ZD (3))

Payments for donors (Guidance Note 13)
A record of the actual expenses incurred, such as transport costs (receipts), together with estimated loss of earnings, paid to sperm donors was reviewed within individual donor logs and found to be compliant with General Direction 0001. A member of staff explained the steps taken by the centre to verify such expenses, which included discussions with the donor and production of original receipts. The donor is also asked to provide signed confirmation of expenses/reimbursement claims. It thus appeared that expenses/reimbursement/payments are, reasonable, have been incurred by the donor in connection with the donation of gametes provided to the centre, and have been incurred by the donor solely within the United Kingdom. (General Direction 0001 (3))

What the centre could do better.

Nothing noted

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

Quality management system (Guidance Note 23)
Since the centre was incorporated within the JD Healthcare group, a robust quality management system (QMS) had been developed, under the supervision of an experienced quality manager (QM). There is a two tier system in place; one generic system covering all JD Healthcare centres and also a specific system for the LSB.
The QM was able to demonstrate all aspects of the electronic QMS via a centre personal computer (pc), including;

- a master index for all documents (standard operating procedures (SOPs), forms, checklists etc)
- quality manual
- quality policy
- quality objectives
- organisational chart

Any documentation requested by the inspection team was provided without delay (SLC 32; 33b).

Following much hard work by all staff the centre was accredited under the ISO9001/2008 scheme by the British Standards Institution (BSI) on 15 November 2010 (certificate number: FS 560839).

A recent quality management review dated 6 October 2010 was provided prior to inspection which gave details of various issues discussed such as;

- a review of previous meetings minutes (July 13, 2010)
- volume and scope of work
- staffing levels
- performance review of third parties
- quality indicator results and analysis (SLC 35)
- audit results and audit schedule update (SLC 36)
- user satisfaction results and analysis
- internal quality assurance and corrective and preventative actions review
- date of next meeting: 14 December 2010

Traceability (Guidance Note 19)
The centre has a 'Traceability of media and consumables' section within its laboratory manual which describes both the purpose and practice of the processes currently in place to record all culture media and laboratory consumables which come into contact with gametes. Batch numbers and expiry dates for all routinely used media and consumables are recorded on a 'Traceability record' sheet. When a specific batch of a product has been exhausted, a new sheet is started containing new batch codes and expiry dates. Each record sheet is allocated a unique 'Traceability record log number' which is recorded on each quarantine donor sample record sheet, as a cross reference to the traceability record sheet in operation at any one time. Examples of previously completed/scanned record sheets were viewed via the electronic QMS (SLC 99; 100; 102).

Documentation reviewed indicated that a traceability audit was undertaken during May 2010 and the results discussed at the May 2010 quality management review meeting (SLC 36).

Traceability quality indicators (QI's) were seen to have been established and to be part of the ongoing audit schedule (SLC 35).

It is stated in the laboratory manual that donor notes will be kept for a period of 30 years (SLC 103).

Validation (Guidance Note 15)
Validation documentation was reviewed and found to be in place for all processes (completed 31/08/10).
All critical equipment, with the exception of the cryo-dewars had been retrospectively validated (SLC 72). Any equipment that requires repair will undergo re-validation prior to being put back into use (SLC 25). As indicated by audit schedules seen, validation audits of all critical processes and equipment were scheduled to be undertaken during 2011 (SLC 36).

Equipment and materials (Guidance Note 26)
There is only one set of critical equipment currently used in the procurement and processing of samples at the centre (SLC 22).

Monitoring of temperatures was seen to be in place for incubator, fridge-freezer and cryo-dewars. Low liquid nitrogen alarms were in place for the cryo-dewars which held the 'cleared' donor samples. These dewars were constantly monitored via connection to a laboratory pc. As indicated by a laboratory log, the levels of liquid nitrogen were seen to be physically measured and replenished every second week (SLC 24).

All critical equipment was seen to have a current service/maintenance contract in place (SLC 23) and were said to be cleansed at the end of each day (SLC 26).

Premises and Facilities (Guidance Note 25)
The licensed premises are all within the same building (Act Schedule 2 S.4(2)(d)) and all activities seen to be carried out within these same licensed premises (SLC 1). A copy of the centres licence was seen to be on display at the centre (SLC 5).

A low oxygen monitor is present on the external wall of the entrance to the laboratory. The quality manager explained that this device was still under warranty as only installed during November 2009, but that a service/maintenance contract has been arranged from December 2010.

A premises cleansing log was reviewed for the period, 26/10/10 to 22/11/10.
Staff stated that the premises are cleansed at the end of every day and more rigorously once a week (SLC 26).

A SOP is in place for the monitoring of air quality both within the critical processing area (flowhood) and the background laboratory environment (SLC 33). The air quality within the flowhood and laboratory background is measured with a particle counter twice a week. An air quality log seen within the laboratory showed that air quality within the flowhood was consistently grade A (SLC 20).

Adverse incidents (Guidance Notes 27)
The quality manager stated that there is a process in place at the centre for reporting adverse incidents, although no incidents had occurred or reported to the Authority since the last inspection (SLC 118). Adverse incidents and reactions from all licensed centres within the JD Healthcare group were seen to be discussed at the latest quality management review held on 6 October 2010. If any adverse incident/reaction did occur there is a SOP in place to report any such event to the Authority within required timeframes. Any such event would be investigated as part of the corrective and preventative actions (CAPA) process and reported to the Authority. (SLC 119).

Third party agreements (Guidance Note 24)
Written third party agreements (TPAs) were seen to have been established with all companies who provide goods/services that may influence the quality/safety of gametes. A sample agreement appeared to be compliant with all regulatory requirements (SLC 111-116). Issues concerning TPAs across JD Healthcare group discussed at last quality management review (06/10/10). The quality manager is to undertake a full risk assessment of the external suppliers of pathological and biochemical laboratory services and report the findings to the next review meeting in December 2010.

What the centre could do better.

Validation (Guidance Note 15)
The centre should retrospectively validate all cryo-dewars and dry-shippers in use at the centre (SLC 72).

Premises and Facilities (Guidance Note 25)
The centre should ensure that background air quality within the laboratory is grade D (SLC 20). This is a persistent issue and there was evidence seen during the inspection to suggest that the daily cleansing regimen was not resolving the situation. The possibility of the introduction of a regular, scheduled ‘deep clean’ of the laboratory area, to help improve the background air quality was discussed during the inspection.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible (Guidance Note 1)

The PR, Dr Kamal Ahuja appears to be a competent, experienced PR and has completed the PR entry programme (PREP) (SLC 8). Under his leadership the centre has undergone much organisational change over the last twelve months in order to achieve broad regulatory compliance (SLC 9).

Staff (Guidance Note 2)

The centre provided an organisational chart which clearly defines accountability and reporting structure, together with a staff list with job titles (SLC 11). The centre has access to a registered medical practitioner who is based at an associated centre in close proximity (SLC 16). The centre has assessed workforce requirements against the volume of work undertaken, as part of the last quality management review on 6 October 2010, and found that staffing levels were adequate to safely deliver the present workload. Competency assessments were seen to be performed and signed off by the line manager (SLC 12).
A new member of staff had a training file which showed that initial induction training was undertaken and signed off by the line manager (SLC 15). The senior Andrologist is registered with the Health Professions Council (HPC) (SLC 14).
Staff explained that they had access to a variety of professional development, including attendance at lectures, online learning, and access to journals (SLC 15).

What the centre could do better.

Nothing noted

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)

What the centre does well.

Treating patients fairly (Guidance Note 29)

The centre staff ensures that all licensed activities are conducted in a non-discriminatory manner with proper respect, dignity, comfort and well being of all current and prospective donors. The centre undertakes regular reviews of donor satisfaction via distribution and analysis of service user questionnaires. The outcomes from the latest donor questionnaires were discussed at the last quality management review on 6 October 2010.

Confidentiality and privacy (Guidance Note 30)

The centre staff ensures that all licensed activities are conducted with proper respect for donor privacy and confidentiality.

Complaints (Guidance Note 28)

The centre has a documented complaints procedure in place, but no complaints have been received by the centre since the last inspection. As part of the quality management review system, complaints form all JD Healthcare licensed centres are collated and reviewed/discussed in order to disseminate any generic or specific learning.

What the centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)

What the centre does well.

Counselling (Guidance Note 3)
During discussions with staff it was established that access to counselling is offered to all prospective donors and available to all on-going donors throughout the donation process. An appropriately qualified counsellor is available to all donors as and when required via mutual arrangement. This information is also available to prospective donors via the centres website.

Evidence of counselling being made available to donors was seen within the laboratory manual and via checklists seen within donor records.

A counselling audit is due to be undertaken in December 2010 as part of the centre's audit schedule (SLC 36).

The quality manager stated that a generic counselling SOP together with generic JD Healthcare counselling quality indicators were in place at the centre (SLC 35).

Information to be provided prior to consent (Guidance Note 4)

The centre has established a website, which gives information about the whole sperm donation process presently undertaken at the centre. The website includes frequently asked questions (FAQs) about the process, including why donors are needed, HFEA regulation, access to counselling, anonymity issues, expense reimbursement for donation, screening, live birth events limits and who shouldn't become a donor.

Prospective donors who make phone enquiries to the centre are taken through the process by a member of staff if required, or can be sent a comprehensive booklet, entitled, 'information for sperm donors', which gives details of the whole donation process if requested.

Donors are given verbal information about the donation process during an initial interview at the centre. A checklist is used by trained and competent staff (SLC 15) to ensure that all required information is given to prospective donors prior to any consents being signed (SLC 58). There is a SOP in place for the provision of information to be provided to prospective donors (SLC 33) and quality indicators have been established (SLC 35). An audit of information given to donors has been undertaken via a review of donor notes (SLC36).

Access to counselling is mentioned on the website, within the information booklet and discussed with staff at the initial interview.

What the centre could do better.

Nothing noted

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

What the centre does well.

Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

Written consent is taken from donors prior to any donated sperm being used for treatment. An audit of donor records undertaken on the day of inspection showed that all relevant consents were present (SLC 57).

Quality indicators have been developed for the process of taking consent and two audits of consents performed as part of the centres audit schedule (SLC 35; 36)

What the centre could do better.

Centre staff were said to obtain written consents as per HFEA guidance note 5, but no evidence of a documented SOP for this procedure was seen to be in place..

3. Protection of gametes and embryos

Focus
The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos where created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.
See section 1.

What the centre could do better.

See section 1

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.
Storage of gametes and embryos (Guidance Note 17)

All gametes in storage at the centre are stored in accordance with donor consents.

A procedure for the storage of gametes is present within the laboratory manual (SLC 33b). The centre presently has eight active cryo-dewars, with cleared samples being kept in two vessels which are continually monitored for liquid nitrogen levels (SLC 24).

An audit of storage times was seen to have been completed as part of the 2010 audit schedule. Appropriate quality indicators were seen to be in place (SLC 36).

The centre was seen to have a monitoring system in place in order to ensure that all stored samples are not stored beyond the time consented to by the donor. There was evidence that all currently stored samples were within the statutory storage period (SLC 79; 80)

What the centre could do better.

Nothing noted

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*

What the centre does well.

Distribution/receipt of gametes and embryos (Guidance Note 15)

The procedure for the receipt/distribution of gametes is described within the laboratory manual, together with a recall procedure (SLC 33b).

All gametes are packaged/transported in a container that is designed for the carriage of biological materials and which minimises the risk of contamination whilst preserving their biological function (SLC 105; 106)

A laboratory checklist for the dispatch of gametes ensures that all necessary procedures have been arranged with the receiving centre and that all required information is supplied. A shipping label specifying transport conditions is affixed to the container (SLC 107).

What the centre could do better.

Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

▶ **Record keeping** • Record keeping and document control (Guidance Note 31)
What the centre does well. **Record keeping and document control (Guidance Note 31)** All donor records reviewed on the day were seen to be legible, well organised and kept securely (SLC 46; 47). The quality manager was able to demonstrate that a document control system was in place for review and revision of documentation in use at the centre (SLC 34). The centre forwards all required information to the Authority within appropriate timescales (SLC 41)
What the centre could do better. Nothing noted.

▶ **Legal requirements** [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the centre does well. The PR provided all required information in relation to the licence renewal application process in good time prior to the inspection (General Direction 0008) All documentation requested during the inspection was promptly supplied by centre staff (SLC 9c) .
What the centre could do better. Nothing noted

5. Changes / improvements since the previous inspection on 14 April 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
The centre does not have a standard operating procedure for the measurement of air quality and could not provide evidence that the processing of gametes takes place in an environment of at least a grade C or a background of grade D.	The PR should ensure that the centre can demonstrate and document that the chosen environment achieves the air quality required.	A SOP is in place for the monitoring of air quality both within the critical processing area (flowhood) and the background laboratory environment (SLC 33). The air quality within the flowhood and laboratory background is measured with a particle counter twice a week. An air quality log seen within the laboratory showed that air quality within the flowhood was consistently grade A (SLC 20). The background air quality within the laboratory still doesn't meet the required grade D.
Witnessing step (1) verifying the identity of the donor at the time of sperm production. This step is carried out but there is no space on the witnessing form for double signatures by staff. The timing of witnessing events is not recorded. A record of witnessing is not kept in the donors' records.	Revision of witnessing form during sample production. Revision of witnessing form to include recording of time that events are witnessed Retention of a witnessing record to be retained within donor records upon completion of donation cycle.	This procedure is now undertaken as required and there are two spaces on the quarantine donor sample record for witnessing to be recorded (SLC 71). Times at which witnessing events are undertaken are now recorded (SLC 71). A witnessing record is now retained within donor records upon completion of the donation cycle (SLC 71).
Staff could not provide evidence that training has been updated as required when procedures change or scientific knowledge develops, or that adequate opportunity for relevant professional development	The PR should ensure that members of staff undergo assessment of competence in their designated tasks and maintain suitable documented evidence.	A new member of staff had a training file which showed that initial induction training was undertaken and signed off by the line manager (SLC 15). Competency assessments were seen to be performed and signed off by the line manager

has been provided.	The PR should ensure that members of staff receive adequate opportunity for relevant professional development	(SLC 12). Staff explained that they had access to a variety of professional development, including attendance at lectures, online learning, and access to journals (SLC 15).
Validation of critical processes and equipment had been started but not completed.	Completion of validation of all critical processes and equipment.	All critical processes and equipment were seen to have been validated with the exception of the cryo-dewars (SLC 72).
The shipping container used for transporting gametes was not labelled with the minimum regulatory requirements.	The PR should ensure that the shipping container used is labelled with the minimum regulatory requirements	This had been addressed by staff during the previous inspection and was seen to be in place during the present inspection (SLC 107).

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None observed.			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The cryo-dewars and dry-shippers currently in use at the centre have not been validated (SLC 72).	The PR should ensure that all cryo-dewars and dry-shippers in use at the centre are retrospectively validated by 28 February 2011.	All cryo-dewars and dry-shippers will be validated by the time specified	To be followed up by centre inspector as part of ongoing monitoring process
The laboratory background air quality is not grade D (SLC 20).	The PR should ensure that background air quality within the laboratory is equivalent to grade D by 28 February 2011.	Measures are being explored to improve the background air quality to a grade D standard by the time specified	To be followed up by centre inspector as part of ongoing monitoring process

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Centre staff were said to obtain written consents as per HFEA guidance note 5, but no evidence of a documented SOP for this procedure was seen to be in place (SLC 33b).	The PR should ensure that a documented SOP is in place when staff take written consent, by 28 February 2011.	The generic J D Healthcare consent SOP will be amended to include the LSB	To be followed up by centre inspector as part of ongoing monitoring process

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

4 February 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Centre 0011 (The London Sperm Bank) – Renewal Inspection Report (Storage Only)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Juliet Tizzard, Head of Policy	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed by the HFEA since April 2010 for the procurement, distribution, processing and storage of sperm.

2. The Panel noted that it was formerly known as the Louis Hughes centre, which was originally licensed in 1992.

3. The Panel noted that the centre presently recruits sperm donors and provides donor sperm to fertility clinics throughout the United Kingdom.

4. The Panel noted that between the previous renewal inspection on 29 October 2009 and the follow-up inspection on 14 April 2010, the centre has undergone a number of significant changes, including the following:

    - A change of ownership: it is now within the JD Healthcare umbrella of HFEA licensed centres (whilst retaining the same HFEA centre number, 0011);

    - A new Person Responsible (PR): Dr Kamal Ahuja has successfully completed the PR Entry programme and has been appointed the new PR (approved by the Panel on 27 January 2010);

    - A new Licence Holder (LH): a new LH has been appointed (approved by the Panel on 11 March 2010);

    - Staff: new staff have been recruited and a new organisational structure developed;

    - Premises: the premises have been refurbished and some new equipment has been purchased, installed and commissioned.

5. The Panel noted that at the time of the inspection on 23 November 2010, there were a number of areas that had been identified by the Inspectorate that required improvement, including two major areas of non-compliance and one other area of non-compliance.

6. The Panel noted that since the inspection the PR has responded positively to the report and has provided an assurance to the Inspectorate that all three areas of non-compliance will be addressed within the prescribed time frame.

7. The Panel noted the Inspectorate recommendation for the renewal of the centre's licence for a period of four years without any additional conditions.

8. The Panel noted the progress made by the centre over the past 12 months and the clear leadership given by the new PR.

9. The Panel had regard to its decision tree. It was satisfied that the application was submitted in the form required, and contained the supporting information as required by General Direction 0008. It was also satisfied that the appropriate fee had been paid.

10. The Panel noted that the centre had submitted an email to the Inspectorate, tabled at the meeting, which clarified the licensable activities they wished the licence to list: Storage of Sperm, Processing of Gametes, Procurement and Distribution of Gametes.

11. The Panel was satisfied that the application designated an individual to act as the PR and that the PR had consented to act as such.

12. The Panel was satisfied the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under Section 17 of the Act. The Panel also noted that the PR had successfully completed the PR Entry Programme.

13. The Panel was satisfied that the licence renewal application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

14. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on the evidence provided within the report.

15. The Panel was satisfied that the application does not involve the use of embryos for training purposes, nor does it involve the testing of embryos.

Decision

16. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states '[The Executive Licensing Panel] will normally only grant a renewal licence for treatments/storage non-medical fertility services for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3'.

17. As it was satisfied that the evidence before it revealed no concerns regarding the requirements set out in paragraph 4.3, the Panel agreed to renew the centre's storage licence for a period of four years with no additional conditions.

18. The Panel endorsed the recommendations made by the Inspectorate, and urged the PR to ensure that all outstanding recommendations are addressed within the specified timeframes, paying particular attention to the recommendation on page 21 of the report in relation to air quality.

Signed: Peter Thompson Date: 14/2/11.

Peter Thompson (Chair)